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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
DIETRICH, JOSEPH M	

ART UNIT	PAPER NUMBER
3762	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/502,349	REZAI ET AL.	
	Examiner	Art Unit	
	Joseph M. Dietrich	3762	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *06 May 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-5,7-37,41 and 42* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-5,7-37,41 and 42* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Response to Arguments

1. Applicant's arguments filed 6 May 2008 have been fully considered but they are not persuasive.

Regarding the 102(e) rejection by Baudino et al., applicant argues that the Baudino reference merely mentions affecting chronic pain and stimulating certain cites of the brain in passing. Applicant argues that this does not amount to a teaching of affecting chronic pain by stimulating those mentioned sites. Examiner disagrees. As set forth in Baudino, "The features and advantages of the present invention for steering an electric field within a brain, a spinal cord, or a peripheral nerve may be implemented in numerous applications. It is generally desirable to excite particular neural tissue elements of the brain to provide a certain treatment such as treatment of a neurological disorder, the relief of chronic pain or to control movements" (e.g. column 9, lines 18 – 24). As shown, Baudino clearly teaches that the present invention is used to treat chronic pain.

Furthermore, applicant argues that a passage set forth in Baudino (column 9, lines 24 - 25) states to avoid the internal capsule. Column 9, lines 24 – 30, states, "Often, nearby groups of neurons or axons, e.g. the optic nerve, internal capsule, or medical lemniscus, are in special orientations and groupings. It may be advantageous to avoid affecting them (e.g. preventing stimulation of the perception of the flashes of light) or deliberately to affect them (e.g., excite or inhibit axons of passage)." As shown, Baudino teaches that it may be advantageous to stimulate certain areas for the

purposes of the invention described by Baudino.

Applicant also argues that the sites mentioned in Baudino column 9, line 61 to column 10, line 9 are mentioned in conjunction with configuration changes of the device and are certainly not linked to any specific disorders, let alone chronic pain. Applicant does not claim any specific configuration other than 'implanting a stimulator in a target site of the brain.' Baudino states that "the present invention may be used to deliver treatment therapy to any number of sites in the brain." Baudino teaches that the present invention excited particular neural tissue elements of the brain to provide a certain treatment such as relief of chronic pain, and that the invention may be used to deliver treatment therapy to any number of sites in the brain.

Applicant argues that Baudino does not describe detecting a bodily activity associated with chronic pain and providing a stimulation signal in response to the detected bodily activity to stimulate the target site to affect chronic pain. However, in column 2, lines 57 – 62, Baudino teaches sensing the physical condition for treating pain and using the signal generated by the sensing to adjust at least one parameter of the electrical energy provided to the electrode. Because the sensor generates a signal related to the extent of a physical condition for treating a neurological disorder or pain, it is considered to be a "bodily activity of the body associated with the chronic pain." Because the signal generated by the sensor adjusts at least one parameter of the electrical energy, it "provides a stimulation signal to the stimulator in response to the detected bodily activity."

Regarding the 102(b) rejection by MacDonald et al., applicant argues that

MacDonald does not describe implanting a stimulator in communication with a pain circuitry target site but rather placing electrodes on the surface of the skin. While MacDonald does teach treating pain through surface electrodes, MacDonald also teaches that "in some circumstances it may be desirable to implant the electrodes" (column 3, lines 49 – 51) and that "if required, the electrodes may be implanted in the body either in tissues near the spine or within the spinal canal itself" (column 8, lines 55 – 57).

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

3. Claims 1, 4, 19, 20, 22, 24, and 36 are rejected under 35 U.S.C. 102(e) as being anticipated by Baudino et al. (U.S. Patent 6,353,762).

Regarding **claims 1 and 4**, Baudino discloses a method of affecting chronic pain in a patient comprising: implanting a stimulator in a target site of the brain (e.g. column 9, lines 61 – 66); detecting a bodily activity of the body associated with chronic pain (e.g. column 2, lines 57 – 60); and providing stimulation to the stimulator in response to

the detected bodily activity to stimulate the target site to affect chronic pain (e.g. column 9, lines 18 – 24), wherein the target site is the anterior limb of the internal capsule (e.g. column 9, line 66).

Regarding **claims 19, 20, 22, 24, and 36**, Baudino discloses the target site is selected from the group consisting of the anterior nucleus of the thalamus (e.g. column 9, line 67), the dorsomedial nucleus of the thalamus (e.g. column 9, line 67), the lateral hypothalamus (e.g. column 10, line 3), and the ventral pallidum (e.g. column 9, line 65).

4. Claim 37 is rejected under 35 U.S.C. 102(b) as anticipated by MacDonald et al. (U.S. Patent 5,776,170).

Regarding **claim 37**, MacDonald discloses a method of affecting chronic pain comprising: a) implanting a stimulator in communication with a pain circuitry target site (e.g. column 8, lines 55 – 57); and b) providing a stimulation signal to the stimulator to stimulate the synthesis or release of an endogenous opioid (e.g. column 3, lines 28 -31) to affect chronic pain (e.g. column 10, lines 4 – 6 and Table 2).

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

6. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

7. Claims 19, 21, 26 – 31, and 33 – 35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Baudino et al., and further in view of Schiff (U.S. Patent 5,938,688).

Regarding **claims 19, 21, 26 – 31, and 33 – 35**, Baudino discloses the claimed invention except for some of the specifically claimed regions of the brain. Schiff teaches it is known to affect chronic pain (e.g. column 2, lines 20 – 23 and 43 – 47) by stimulating a target site, wherein the target site is selected from the group consisting of the intralaminar thalamic nuclei (e.g. column 4, lines 58 – 61), locus coeruleus (e.g. column 8, line 20), dorsal raphe nucleus (e.g. column 8, line 20), substantia nigra pars compacta (e.g. columns 9 and 10, Table 1), substantia nigra pars reticulate (e.g. columns 9 and 10, Table 1), superior colliculus (e.g. columns 9 and 10, Table 1), tegmentum (e.g. column 8, line 19), medial thalamus (e.g. column 14, lines 45 – 50), nucleus accumbens (e.g. column 13, lines 5 – 6), ventral striatum (e.g. column 8, line 2). Because Schiff discloses that patients with impaired cognitive function accompanied by chronic pain can benefit from the practice of Schiff's invention, Schiff teaches that chronic pain is affected by this method. In the alternative, it would have been obvious to

one having ordinary skill in the art at the time the invention was made to modify the method as taught by Schiff so as to treat patients with only chronic pain, since such a modification would provide the predictable results of affecting chronic pain.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the sites of the brain as taught by Baudino with the claimed sites of the brain as taught by Schiff, since such a modification would provide the predictable results stimulating only the regions that optimize the therapeutic results felt by the patient and avoiding inadvertently stimulating surrounding areas of the brain.

8. Claims 1 – 36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Baudino.

Regarding **claims 1 – 36**, although Baudino fail to explicitly state stimulating the insular cortex, the secondary somatosensory cortex, the inferior frontal gyrus, the middle frontal gyrus, the superior frontal gyrus, the medical frontal gyrus, the parahippocampal gyrus, the precuneus, the mammillary body, and the tectum, these references do teach that it is known to stimulate other cortical sites (e.g. the pre-frontal cortex) and other deep brain sites (e.g. the intralaminar nuclei) in order to affect chronic pain. It would have been obvious to one having ordinary skill in the art at the time the invention was made to try to stimulate these other cortical and deep brain sites in the brain since these references teach that it is known to stimulate cortical sites and deep brain sites to affect chronic pain and there are a finite number of cortical sites and deep

brain sites and determining the best site to stimulate in the brain would be obvious to one having ordinary skill in the art.

9. Claims 41 and 42 rejected under 35 U.S.C. 103(a) as being unpatentable over MacDonald et al. as applied to claim 37 above, and further in view of Baudino et al. or Schiff.

Regarding **claims 41 and 42**, MacDonald discloses the claimed invention except for the specific claimed areas of the brain. Both Baudino and Schiff teach affecting chronic pain by stimulating the specific claimed areas of the brained as described above. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the stimulation site as taught by MacDonald with the claimed sites of the brain as taught by either Baudino or Schiff, since such a modification would provide the predictable results stimulating only the regions that optimize the therapeutic results felt by the patient and avoiding inadvertently stimulating surrounding areas of the brain.

Conclusion

1. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not

mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Joseph M. Dietrich whose telephone number is (571)270-1895. The examiner can normally be reached on M-F, 8:00 - 5:00 EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on 571-272-4955. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/J. M. D./
Examiner, Art Unit 3762
9/10/08

/George R Evanisko/
Primary Examiner, Art Unit 3762